The Role of Foreign Governments

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Overview of Presentation:

• What we are trying to achieve
• The role of Governments
• Some confusion in the terminology
• Talk a little bit about the relevant international standard
• Promote the FDA’s system comparability assessment process
What My Group does

• Import & Export Standards for Foods
  • + exports of wine, organics, grade, animal feeds, wool, hides & skins

• Export Certification programmes

• International Regulatory Relationships

• International Standards
Assurance Programs

• President Lincoln used to say:
  • Trust but Verify

• There is a similar saying in the Middle East:
  • Trust in God but tie up your camel
Some People’s Perception of Imports
Some Reality Checks

• Most traded food is safe – big companies rely on repeat business.
  – There are multiple commercial imperatives

• We collectively are trying to come up with systems which **better target the poor performers** (importers/supplier/country combinations)
Some Reality Checks

- For systems to work they need to be logical, credible, readily achievable, and cost effective.

- Most importantly there needs to be incentives for performance.
Some Reality Checks

• Not all sources of food are comparable

• Not all types of assurance are comparable

• One type of approach does not fit all
New Zealand’s Approach

• Government to government agreements between comparable competent authorities provides the highest level of assurance

• The FDA’s system comparability assessment process is a “gold standard”
Role of Governments

- To provide an appropriate standards & legislative base to prohibit both the domestic sale and the export of unsafe food
- To ensure there is an appropriate level of verification
- To take appropriate enforcement actions should such a sale or export occur
New Zealand Regulatory Model

Consumers

Industry (HACCP)

Accredited Verifiers (ISO 17020)

Regulator

Set standards for consumer protection
Provide assurance(s)
[approve RMPs (HACCP plans), Recognised people and recognised agencies]

Meet standards using Risk Based Management Plans

Independent Audit of how govt requirements are met

Truthfully labeled, safe and wholesome food/beverages

[Image of regulatory model diagram with arrows and text indicating the flow of responsibilities and standards from consumers to industry, through verifiers, and to the regulator.]
Role of Government

- Where justified and agreed with another government, set up a supplementary assurance system which allows the provision of assurances that the exported / certified food / facility meets any agreed additional requirements (outcomes / level of protection) justified by the importing government
NZFSA Regulatory Model

- **CIG**
- **assess**
- **audit**
- **NZFSA**
- **Independent Verification auditing**
- **Industry**
Regulatory Model
Importing Country relationship with New Zealand

- **External Review**
  - Assess performance against negotiated standards

- **New Zealand Competent Authority**
  - Set standards, assess programme performance
  - Provide official assurances through certification

- **Third party verification**
  - Assess processors’ performance
  - Ensures compliance, ‘authenticate’ exports

- **Regulated Industries**
  - Meet standards

- **Regulator**
  - AUDIT

- **Independent Verifiers**
  - ‘AUDIT’

- **Industry**
  - Risk based Food Control Plans
  - Processors and ASURE

- **Importing Country Competent Authority**
  - Sample audit at port of entry
  - Sample audit at next two levels to judge integrity of Competent Authority

Risk based Food Control Plans
Role of Government

- Essentially to act as the agent of the foreign government to ensure the level of protection required by that government is assured.
Audit Burden

• By government recognised agencies

• Direct by central government

• By foreign governments

• Multiple commercial audits
Third-Party Certification

• What is meant by “Third-Party”
  • Confusing terminology
  • Appears to not differentiate “private assurance schemes” from government
  • Confuses audit with certification
  • Confuses the concepts of approval, due diligence and certification
Third-Party Certification

• The relevant international standard talks about

  • Official Certification Systems &

  • Officially Recognised Certification Systems
In the relevant international standard

• Official means Government

• Officially recognised means recognised by the Government having jurisdiction

• Jurisdiction means within the country where the activity is occurring
• This is not to say the importing country does not have the option of not recognising Official certification from any government body or government recognised body that it does not have confidence in.

• But one government can not unilaterally ignore the sovereignty of another and in a trade dispute the relevant parties are the two governments
What is being certified?

• The competency of food control systems relative to a defined level of protection (outcome)

  • Again the relevant international standard is helpful

• Trading countries should identify the main objectives to be addressed through import & export inspection and certification systems.
• “Normally requires an appropriate legislative base, controls, procedures, facilities, equipment, laboratories, transportation, communications, personnel, and training to support the objectives”
Third-Party Certification

• Private “Third-Party Certification” systems can and do work for specific situations.

• However, without a legislative base the setting up of an appropriate food control or food assurance system with a wider scope can be challenging.
Audit versus Certification

• **Audit**: “a systematic & functionally independent examination to determine whether activities & related results comply with planned objectives”

• Audit bodies can be government or can be entities / agencies recognised by the jurisdictional government
Audit versus Certification

• Certification: “Is the procedure by which Official or Officially recognised certification bodies provide written or equivalent assurance that foods or food control systems conform to requirements” (regulatory)

• Requires due knowledge of and control over the system being certified
Third-Party inputs into Certification

• Many Official Certification systems use the services of Recognised Agencies.

• Such agencies may be audit bodies, laboratories, or other service providers

• One of the qualifying criteria for recognition may be accreditation to an internationally recognised quality system standard e.g. ISO 17020 for verification bodies or ISO 17025 for Laboratories
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System Comparability Assessments:

- How did we get into being the “test dummy”
Initial Drivers for Change

- Long history of compliant trade both ways
- We wanted to evolve our relationship
- Long history of alignment & cooperation
- Understood we needed to be smarter with our resources
Initial concern!
Our Backup Plan
What is System Comparability?

- You can always find differences, some real – many really just exist on paper.

- Everyone’s laws are different – this is actually a good thing

- There will always be different hazard profiles

- What we collectively focussed on was what was conceptually important to achieve the necessary food safety assurance outcome.
System Comparability

- Is not about the differences in the way things are done or described, it is about whether the system is designed to appropriately control whatever inherent risks are associated with food production in the exporting country so that the residual risk to human health emanating from each system is comparable.

- It's about focusing on the macro components as these are what ultimately deliver assurances.
Some things you can’t Control

Which Country is this Picture from?
Competent Authority Competency

- Shared public health goals
- Adequate resources
- Freedom from conflict of interest
- Transparency of standards & verification activity
- Demonstrated willingness to take safeguard/enforcement actions
- Commitment to science and risk assessment
- Ongoing monitoring and surveillance programs
The five Rs of Comparability:

- Regulatory base
- Resource
- Risk focus
- Responsiveness
- Regular review
Its also about the 6 “C”s

- Commitment
- Competency
- Cooperative environment
- Continual improvement
- Compliance & enforcement
- Coverage of potential Conflicts
Let's not forget the 2 “S”s & the “T”

- Science-based assessments and standards
- Safeguard actions
- Transparency
Based on a comprehensive analysis of the food control system in the country where it operates you are confident that the system is likely to deliver the same (or better) level of food safety protection as your own provides within your own country.

System comparability is not the same as.

There will always be differences
Differences in the laws, administrative structures and differences in the guidance and standards are not what is important.

It is whether they are fit for purpose and achieve the necessary outcomes for product from that country.
Key Issues:

- It is not about looking to see if there are different hazard profiles.

- For example, the US may have more pathogens, and use more veterinary drugs and pesticides than New Zealand.

- The fact that both of us have appropriate control and monitoring systems & use these results to inform & improve our food control systems is what gives confidence.
Key Issues:

- It is also not necessarily about looking to see if two countries have similar levels of human health burden for any particular disease.

- The reasons for disease stats are multifactorial e.g. countries like US & the NZ may have higher rates of food born illness than those countries that don’t look for it.

- Again the fact that both of us do look & monitor & use these results to inform & improve our food control systems is what gives confidence.
Challenges

- Most regulatory systems tend to still be process prescriptive and hazard focussed and not risk based.

- For International trade there will always be difficulty in judging whether equivalent outcomes are achieved when sanitary measures are solely described as process requirements.

- Accordingly it is necessary to look for comparability of objectives and approach.
Confidence that each Regulatory System is appropriately set up and is competently managed across a broad range of food types so that the overall level of consumer protection imparted will not be significantly different.

System Comparability = System Equivalence
What helped

- High degree of historical alignment of approaches, statutes, regulations and standards

- High level of pre-existing knowledge, confidence & experience

- Guidance from various international standards

- Huge amount of goodwill on both sides
What worked Well?

- High level of commitment on both sides
- Resources on both side dedicated to the process
- Focus was clearly on the objectives behind the legislation and whether the systems were designed to achieve the same public health outcomes
- Focused on haystacks not needles
What worked Well?

- Long term personal relationships helped thrash out common understandings and the confidence to throw ourselves head first into the process
- Development of close collegial relationships amongst the technical experts
- The setting of tight deadlines
- Regularly getting on a plane or the phone for discussions
What worked Well?

- Five coordinated in country expert review teams focussing on different components lead by a senior CFSAN official.

- Each escorted by New Zealand compliance and or standards expert with full authority to visit any premises and pull any record.

- Good relationships with all regulated parties, even when we had to keep changing the program at short notice (more later)
Expected Outcomes

- Each Competent Authority accepted as acting as the other’s Risk Manager

- Safe foods traded freely – with expedited clearance

- Enhanced Cooperation / continued alignment

- Ability to target our resources at less controlled imports
Expected Outcomes

- Importers do not have to request duplicate information / assurances from NZ exporters (the comparability assessment serves as the recognised due diligence under the FSMA e.g. for the voluntary qualified importer program).

- FDA utilises its established knowledge, confidence & experience in MAF’s regulatory control system rather than separately coming to audit commercial premises (higher level of assurance / more cost effective).
Expected Outcomes

- Commodity MOUs are updated, extended and made reciprocal providing both a recognition of comparability and the ability to continue to independently evolve.

- The conditions of trade as noted by importers and exporters are noticeably different as of 1 July 2011 compared to 1 July 2010.

- The assessment is used to look at further areas of cooperation, alignment and resource sharing.
Conclusions

- The process is not for everybody
- Requires a high level of pre-existing alignment & experience
- Is very comprehensive and resource intensive
Conclusions

- Must result in future resource savings and efficiencies
- Will result in much higher levels of assurance than achieved from port of entry inspections and commercial assurances
- Must result in improved conditions of trade
Some things of course are hard to compare!